

## Remarks

A. The Examiner has appropriately rejected claim 13 under 35 U.S.C 112, second paragraph.

Response:

Claim 13 has been canceled.

B. The Examiner has rejected claims 1 -17 under 35 U.S.C. 102(b) as being anticipated by Yoshikawa (D 333,182). The Examiner has also rejected claims 1 -17 as being anticipated by McGill et al (2002/0072730 A1).

Response:

### Claims 1 – 6

Independent claim 1 has been amended to include the limitations of the torquer of the present invention being a one-piece, disposable device. Further, claim 1 now includes the limitations that the proximal slit is defined horizontally within half the width of the flap hinge, and the distal slit is defined vertically within the length of the clamping tongue. The specification has been amended to use identical language of the clamping tongue having a length, which is both inherent, and shown throughout the figures. The proximal slit defined within one-half the width of the flap hinge is disclosed in paragraph 38 of applicant's specification.

Firstly, the device taught by figure 8c of McGill is not a one-piece device. The adapter includes potentially detachable and breakable ridged pads (160a), flexure members (154), clips that fit within cavities (156a), and a non-integrated thumb wheel (134). The McGill adapter is not meant to be quickly discarded after use, and it can not be made as a one-piece mold. Support for the present limitation may be found in paragraph 22 of applicant's specification.

Secondly, as was previously claimed in claim 1, the clamping tongue of the present invention is disposed downwardly from the top *distal end*. In McGill, the clamping mechanism (150 in figure 8c) is positioned in the middle of the adapter. The Examiner indicates that McGill shows a clamping tongue disposed downward from the

top arm, but as shown, this “locking pin” of McGill is not disposed downwardly from the top distal *end* of the top arm, as claimed by independent claim 1. In fact, the locking pin is disposed on the bottom arm of the adapter and in the middle thereof. In order to anticipate a claim, the reference must teach every element of the claim, and McGill does not teach a clamping tongue disposed downwardly from the top distal end and therefore cannot anticipate this claim.

Regardless, claim 1 also includes limitations of both a horizontal slit *and* a vertical slit. Specifically, as now claimed, a proximal slit is defined horizontally within half the width of the flap hinge, and the distal slit is defined vertically within the length of the clamping tongue. The examiner cites 158a in figure 8c to argue these limitations are taught. Assuming *arguendo* that a horizontal slit is shown by 158a, applicant fails to see where the vertical slit is defined. The only slits that are shown in McGill are the centrally disposed channel members in which the guide wire is positioned. These are all aligned axially and only horizontally. There is no distal slit defined vertically within the clamping tongue, as claimed in the present invention, and even if the channel members of McGill can be construed as being horizontal slits, McGill certainly does not teach a proximal slit defined within half the width of the flap hinge. There are no slits at all within the hinge of McGill, nor are there slits within the same locking pin that the Examiner argued was the clamping tongue. Even if a horizontal slit was defined anywhere in the adapter of McGill, there certainly is no vertically defined distal slit. Therefore, McGill cannot anticipate independent claim 1.

With reference to amended independent claim 1 and the reference to Yoshikama, Yoshikama does not show any slit at all. In fact, Yoshikawa shows small holes, which is exactly what the present invention teaches away from. The use of slits as opposed to holes is a non-trivial claim feature of the present invention as distinctly claimed. The use of holes as in Yoshikama requires the device be threaded onto the guidewire from the end of the guidewire. As described by paragraph 12 of applicant’s invention “this necessitates the complete removal of the torquer from the guidewire by sliding the torquer to the proximal end of the guidewire. The guidewire being of considerable length, this relates to several awkward motions which again can cause damage to the intima of the vessel.” Note the small holes of Yoshikama in figures 1, 4 and 5. Yoshikama does

not show a proximal slit defined horizontally within half the width of said flap hinge. As such, Yoshikama's device cannot be slid on the from the side and "fastened to the guidewire 2 by aligning and sliding the proximal slit 50 onto the guidewire 2 with the torquer 1 in an open position (see FIG. 5). The guidewire 2 is then snapped into the two groups of projections 34 (as further described) which entrap the guidewire 2 and allow for easy sliding of the torquer 1" (See Applicant's specification paragraph 38)." Yoshikama further does not show a distal slit defined vertically within the length of the clamping tongue. Therefore, for multiple reasons, Yoshikama does not anticipate claim 1 of the applicant's invention.

Neither Yoshikama nor McGill anticipate amended claim 1. Anticipation under 35 U.S.C. 102(b) arises where a reference teaches *every* aspect of the claimed invention. Anticipation is established only when a single prior art reference discloses, expressly or under principles of inherency, each and every element of a claimed invention. *RCA Corp. v. Applied Digital Data Systems, Inc.*, 730 F.2d 1440, 1444 (Fed. Cir. 1984). Independent claim 1 is patentably distinguishable over McGill, Yoshikama, and the prior art. Claims 2-6 rise or fall with claim 1. Support for the above limitations can be found in paragraphs [0022], [0036], [0038], figs. 1-3, 6. Therefore, claims 1 – 6 are allowable as amended.

#### Claims 7 – 12

Independent claim 7 has been amended to include the limitations of the wire channel means on the top surface further comprising "multiple and alternating projections integrally formed thereon in spaced apart relation; each said projection having formed thereon a longitudinal groove, whereby said guidewire can be nested while allowing the guidewire to rotate freely and move longitudinally within said torquer when in an unlocked position, and further preventing said torquer from falling off said guidewire when in an unlocked position."

Neither Yoshikama nor McGill teach such limitations. Firstly, the alleged "wire channel" in McGill includes *aligned* clamps as opposed to *alternating* projections. The same arrangement of projections on the bottom arm is also not shown by Yoshikama. In fact, there is no figure in Yoshikama which allows one to see the interior of the clamping device.

Secondly, as now indicated in amended claim 7, each projection has a longitudinal groove. This longitudinal groove, or detent, is shown on figure 1, label 34a in applicant's drawings. Also see paragraph 39. "A longitudinal groove 34a or detent is formed on each projection 34 of the bottom arm 15. Each groove 34a further nests the guidewire 2 while allowing the guidewire 2 to rotate freely and move longitudinally within the torquer 1. In an unlocked position, the torquer 1 can advance rapidly along the wire and easily be positioned. The grooves 34a also prevent the torquer 1 from falling off the guidewire in an unlocked position. The guidewire 2 fits into each groove 34a, and a second compression or "snap" of the torquer 1 closes the two arms and "locks" the torquer 1 into a position on the guidewire 2 so that the torquer 1 can rotate and advance the guidewire 2." These longitudinal grooves on the bottoms of the projections are not expressly or inherently shown or described by the prior art. Support for the above limitations can be found in paragraph [0039], figs. 1-2. Accordingly, amended claims 7 – 12 are allowable.

#### Claims 13 – 17

Claims 13 – 17 have been canceled.

### CONCLUSION

Independent claim 1 distinctly claims both the horizontally defined proximal slit traveling half the width of the flap hinge and the vertically defined distal slit within the clamping tongue, which clamping tongue is disposed downwardly from the top distal end. Claims 2 – 6 are dependent from claim 1.

Independent claim 7 distinctly claims a wire channel means embodiment which includes alternating projections, with each projection having a longitudinal groove (or detent), whereby said guidewire can be nested while allowing the guidewire to rotate freely and move longitudinally within said torquer when in an unlocked position, and further preventing said torquer from falling off said guidewire when in an unlocked position. Claims 8 -12 are dependent from claim 7.

Accordingly, it is respectfully requested that this amendment and response be entered. Claims 1 – 12 are allowable under 35 U.S.C. §112 and are no longer anticipated under 35 U.S.C. §102. Should other informal matters remain before a notice of

allowance is issued for this case, please let me know. Thank you for your attention to this matter.

Respectfully submitted,  
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